

### **REMARKS**

Claims 1-18, 21, 24-34 and 36-38 are currently pending in the application, as amended. Claim 1 has been amended to more positively recite that “the instrument [is] configured to output data of each test result combined with the unique identification code.” Support for the amendment to claim 1 can be found in, among other places, the original claims, such as claim original claims 1 and 35; the original Specification at paragraph [041]; and in Figs. 4A-4B. Accordingly, no new matter has been added.

### ***Interview Summary***

The Applicants wish to thank Primary Examiner Kaj K. Olsen for extending the courtesy of a personal interview on Friday, November 4, 2005, with the Applicants’ undersigned patent agent. The contents of a previously e-mailed draft version of a proposed claim amendment were discussed in detail.

In particular, the Applicants’ patent agent discussed a proposed amendment to claim 1 to more positively recite that “the instrument [is] configured to output data of each test result combined with the unique identification code.” The Examiner agreed to this suggested language.

The Applicants’ patent agent discussed why it would not be obvious to modify U.S. Patent No. 5,108,889 (“Smith”), without acquiescing that U.S. Patent No. 5,096,669 (“Lauks *et al.*,” hereinafter, “Lauks”) and U.S. Patent No. 6,153,085 (“Patko *et al.*,” hereinafter, “Patko”) are combinable. Smith already discloses an assay instrument with disposable sensors 352 (Fig. 5) that has a serial number associated with the instrument (col. 52, line 66 – col. 53, line 8 and col. 56, lines 46-65). Additionally, Smith discloses transmitting the data to a physician’s computer for data acceptance, storage and processing (col. 26, lines 29-56) in a TRANSMIT mode (col. 53, lines 57-64). Smith discloses an instrument able to be customized having disposable sensors and a serial number and Smith discloses transmitting the data for further

analysis, but Smith fails to disclose or suggest associating the instrument serial number (i.e., a unique identification code) with the data for each test result.

The Examiner agreed that Smith does not render obvious transmitting the unique identification code with the data. The Examiner indicated that he will withdraw Smith if the code function is explicitly recited in claim 1. Accordingly, Applicants have amended claim 1 as agreed with the Examiner.

***Rejections Under 35 U.S.C. § 103(a)***

**Rejection of Claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38**

Claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Lauks in view of Patko and Smith.

Withdrawal of the rejection of claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

**Claim 1**

Claim 1, as amended, recites, *inter alia*:

a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells, each test cell containing a fluid to be tested, the instrument for performing a diagnostic test selected from said plurality of tests upon the fluid within a selected test cell, the instrument including a reader which reads indicia on the selected test cell prior to engagement of the test cell, the diagnostic test to be performed being selected by the instrument based upon identification information obtained from the indicia on the selected test cell, the instrument further including a unique identification code that provides positive identification of each test result provided by the instrument and the instrument being configured to output data of each test result combined with the unique identification code.... [underline emphasis added]

Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result provided by the instrument and the instrument [is] configured to output data of each test result combined with the unique identification code.

The Examiner acknowledges that Lauks and Patko each fail to disclose a unique identification code for an electronic test instrument, in general, because the Examiner relies on Smith to attempt to provide such a unique identification code (actually a serial number in Smith). The Examiner points to column 52, line 66 through column 53, line 8 of Smith which recites:

A reset at 800 occurs when the system is first powered up and each time the lancet firing button 116 is pressed. If both F and S buttons, at 802, are pressed, the SET UP mode at 804 is entered. *The SET UP mode at 804 will be used at the factory or other locations to customize each instrument as to the specific characteristics. These characteristics may include, but are not limited to: serial number, date of manufacture, type of analyte, 12 or 24 hour clock, United States or International display format, units of concentration, look up tables, etc. [emphasis added]*

The Examiner agrees that the language suggests that the “assay instrument” of Smith *has* a serial number for identifying an assay instrument. However, Smith fails to disclose or suggest that such a serial number is used to identify which instrument provided a particular test result or provided other data. The two passages cited by the Examiner are the *only* two instances where the serial number is even mentioned in Smith.

To establish *prima facie* obviousness of a claimed invention, all the claim ’s limitations must be taught or suggested by the prior art. M.P.E.P. § 2143.03. Lauks and Patko and modified by Smith fail to disclose or suggest all the claim limitations of claim 1. Modifying Lauks and Patko to include the serial number of Smith still fails to disclose that the instrument has a unique identification code that provides positive identification of each test result provided by the

instrument and that the instrument [is] configured to output data of each test result combined with the unique identification code, as set forth in independent claim 1.

Moreover, as set forth in detail in the Amendment filed on October 14, 2004, the Applicants maintain that Lauks and Patko are not properly combinable.

Applicants respectfully submit that the combination of Smith with Lauks fails to provide the motivation to further modify the combined devices to uniquely identify test data produced by a particular instrument.

Notably, Smith already discloses that the instrument can transfer data in a TRANSMIT mode using an audible generator output (see for example, column 55, lines 54-58: “[t]his mode TRANSMITS at 957 previously stored assay data via 300 baud Bell Telephone standard format.”). Smith discloses transmitting the data to a physician’s computer for data acceptance, storage and processing (col. 26, lines 29-56) in a TRANSMIT mode (col. 53, lines 57-64).

Yet, there is no suggestion in Smith of using the serial number to be associated with particular test data sampled. Still the Examiner asserts that using the serial number from Smith and the customizable tables to modify Lauks, which did not include a serial number or other unique identifier for the instrument at all, would provide one with the motivation to modify the two references. Modifying Lauks to include the features of Smith results in a device that is already disclosed in Smith. Combining Smith and Lauks yields what is already disclosed in Smith sans any motivation to modify the combined device beyond what Smith discloses. As mentioned above, Smith fails to recognize that the instrument has a unique identification code that provides positive identification of each test result provided by the instrument.

During the aforementioned interview of November 4, 2005, the Examiner agreed that amended claim 1 does not render obvious transmitting the unique identification code combined with the data of each test result and that the Examiner will withdraw Smith.

Claims 2-12, 17-18, 21, 24, 26-28, 30 and 36-38 all depend from claim 1. Applicants respectfully submit that claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 are not prima facie obvious under 35 U.S.C. § 103(a) in view of Lauks and Patko and modified by Smith.

Accordingly, Applicants respectfully request that the rejection of claims 1-12, 17-18, 21, 24, 26-28, 30 and 36-38 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 13-16

Claims 13-16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Lauks, Patko and Smith and further in view of U.S. Patent No. 4,797,188 ("Tomita").

Withdrawal of the rejection of claims 13-16 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

Claims 13-16

Claims 13-16 are dependent upon independent claim 1.

Further, for all of the reasons cited above with respect to claim 1, Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result provided by the instrument and the instrument [is] configured to output data of each test result combined with the unique identification code.

Tomita fails to compensate for the deficiencies of Lauks, Patko and Smith. Tomita merely discloses a sheet type electrode for use in measurement of ions and fails to disclose or suggest an electronic instrument having a unique positive identification code to associate with data acquired from such an electrode.

During the aforementioned interview of November 4, 2005, the Examiner agreed that amended claim 1 does not render obvious transmitting the unique identification code combined with the data of each test result and that the Examiner will withdraw Smith.

Applicants respectfully submit that claims 13-16 are not *prima facie* obvious under 35 U.S.C. § 103(a) in view of Lauks, Patko, Smith and Tomita. Accordingly, Applicants respectfully request that the rejection of 13-16 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 25 and 27-29

Claims 25 and 27-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Lauks, Patko and Smith and further in view of U.S. Patent No. 4,798,705 (“Jakubowicz *et al.*,” hereinafter, “Jakubowicz”).

Withdrawal of the rejection of claims 25 and 27-29 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

Claims 25 and 27-29

Claims 25 and 27-29 are dependent upon independent claim 1.

Further, for all of the reasons cited above with respect to claim 1, Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result provided by the instrument and the instrument [is] configured to output data of each test result combined with the unique identification code.

Jakubowicz fails to compensate for the deficiencies of Lauks, Patko and Smith. Jakubowicz discloses a “compact analyzer” with a keyboard, a 4-line liquid crystal display and a

thermal dot matrix printer. But, there is no suggestion in Jakubowicz that the compact analyzer has a unique identification code or that such a unique identification code be utilized with acquired/produced test data.

During the aforementioned interview of November 4, 2005, the Examiner agreed that amended claim 1 does not render obvious transmitting the unique identification code combined with the data of each test result and that the Examiner will withdraw Smith.

Applicants respectfully submit that claims 25 and 27-29 are not *prima facie* obvious under 35 U.S.C. § 103(a) in view of Lauks, Patko, Smith and Jakubowicz. Accordingly, Applicants respectfully request that the rejection of 25 and 27-29 under 35 U.S.C. § 103(a) be withdrawn.

#### Rejection of Claims 31-34

Claims 31-34 have been rejected under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Lauks, Patko and Smith and further in view of U.S. Patent No. 5,405,510 ("Betts *et al.*," hereinafter, "Betts").

Withdrawal of the rejection of claims 31-34 is respectfully requested in view of the foregoing amendment to claim 1 and for at least the following reasons.

#### Claims 31-34

Claims 31-34 are dependent upon independent claim 1.

Further, for all of the reasons cited above with respect to claim 1, Lauks, Patko and Smith, taken alone or in combination, all fail to disclose or suggest a hand held portable, self contained electronic instrument for engaging any one of a plurality of disposable test cells that include[es] a unique identification code that provides positive identification of each test result

provided by the instrument and the instrument [is] configured to output data of each test result combined with the unique identification code.

Betts fails to compensate for the deficiencies of Lauks, Patko and Smith. Betts discloses portable analyte measuring systems that can be AC or DC powered, that have batteries and that each have a central processing unit that communicates externally via RS232. However, there is no suggestion in Betts that the portable analyte measuring systems have a unique identification code or that such a unique identification code be utilized with acquired/produced test data.

During the aforementioned interview of November 4, 2005, the Examiner agreed that amended claim 1 does not render obvious transmitting the unique identification code combined with the data of each test result and that the Examiner will withdraw Smith.

Applicants respectfully submit that claims 31-34 are not *prima facie* obvious under 35 U.S.C. § 103(a) in view of Lauks, Patko, Smith and Betts. Accordingly, Applicants respectfully request that the rejection of 31-34 under 35 U.S.C. § 103(a) be withdrawn.



**CONCLUSION**

In view of the foregoing Amendment and Remarks, it is respectfully submitted that claims 1-18, 21, 24-34 and 36-38, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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